

use might result in dependence upon a laxative and that a laxative should not be taken when suffering from nausea, vomiting, abdominal pain, or other symptoms of appendicitis; and (3) in that the following statements on the label, "To assist in relieving headaches, coated tongue, bad breath, aggravated pimply skin, lassitude, indigestion and other distressing symptoms due to temporary constipation," and similar statements in Spanish, borne on the label, were false and misleading since the article would not be efficacious for the purposes recommended.

Dye's Compound Tablets were alleged to be misbranded in that statements on the label which represented that it would relieve the distressing symptom of functional dysmenorrhea, painful symptoms of certain female functional irregularities, and symptoms such as headache, nervousness, irritability, headache, backache, nausea, debility, rings under the eyes, melancholia, hysteria, loss of appetite, lack of sleep, and pains in various parts of the body; that it would build up physical resistance, improve digestion and assist one in obtaining more nourishment; that it would promote happy life and would increase vitality and personal magnetism, thus making every attractive woman full of animation; and that it was an appropriate preventive and treatment for amenorrhea, dysmenorrhea, menopause, menorrhagia, metritis, and ovaritis, were false and misleading since it contained no ingredients capable of producing such effects. Both products were alleged to be misbranded further in that the containers were so filled as to be misleading.

On August 14 and October 6, 1941, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

615. Misbranding of Fernel Concentrate. U. S. v. 65 Bottles, 144 Bottles, and 237 Bottles of Fernel Concentrate. Default decrees of condemnation and destruction. (F. D. C. Nos. 4797, 6133, 6274. Sample Nos. 43436-E, 43901-E, 62944-E, 62997-E.)

In addition to failure to bear adequate directions for use and warning statements, the labeling of this product also contained false and misleading claims.

On or about June 2 and November 1 and 22, 1941, the United States attorneys for the District of Kansas and the Eastern District of Michigan filed libels against 65 bottles of Fernel Concentrate at Wichita, Kans., and 381 bottles of Fernel Concentrate at Detroit, Mich., alleging that the article had been shipped within the period from on or about February 21 to on or about November 15, 1941, by the Fernel Co. from Chicago, Ill., and from Kansas City, Mo.; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted essentially of Epsom salt, extract of cascara sagrada, small proportions of magnesium carbonate, sodium phosphate, salt, iron and ammonium citrate, a sugar, saccharin, alcohol, and water.

The portion of the product located at Detroit was alleged to be misbranded: (1) In that the directions for use appearing on the label, "Average Directions for Taking Adults: Take two tablespoonsful before going to bed and one tablespoonful before or after each meal. As this preparation contains laxative as well as other ingredients, regulate the dose according to action on bowels. You should have two thorough bowel actions a day. Above dose is average, but decrease or increase as agreeable," were not adequate directions for use since the article was essentially a laxative drug and the said directions for use included no limitation on the duration of administration but suggested use for an indefinite period by reason of the following statement appearing in an accompanying leaflet, "Valuable Coupon Read Carefully When you have Three of these coupons, mail to Company as below and we will mail you promptly prepaid one bottle of Fernel Free. Just go to your druggist and buy two more bottles of Fernel and you will then have three coupons." (2) In that the statement appearing in an accompanying leaflet, "Send For 'The Fernel Method' Send penny post card or letter to Fernel Co., 800 N. Clark St., Chicago, Illinois for instructive information on the Fernel Method. It will be mailed you postage paid," referred to two other leaflets entitled "The Fernel Method of Weight Reduction" and "Proof," and by such reference incorporated in the labeling of the article the statement appearing in these two leaflets, and that these statements, which represented that the article was a safe or appropriate means of reducing weight, would improve the whole system, overcome arthritis, enable one to do hard work without feeling worn out, prevent one from becoming tired after working all day, make one feel fine, relieve stuffiness around

the heart, make one feel healthier or look younger, give more energy, act as a tonic, relieve chronic constipation, help in every way, prevent headaches, or remedy gall-bladder trouble, were false and misleading since the article would not be efficacious for such purposes.

The portion located at Kansas City was alleged to be misbranded: (1) In that the labeling failed to bear adequate warnings against use by children where its use might be dangerous to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since the label bore no warning that frequent or continued use of the preparation might result in dependence on laxatives to move the bowels. (2) In that the warning on the label with reference to the avoidance of use of the article in the presence of symptoms of appendicitis was not prominently placed thereon with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use, since it appeared relatively inconspicuously on one panel of the label attached to the package as sold and did not appear in connection with the directions for use on the label headed "Paste This Label On Your Bottle After Making." (3) In that the name Fernol and the statements appearing in the labeling constituted a device that was false and misleading since it suggested and represented to purchasers that the article would be appropriate and effective in the treatment of obesity; whereas it would not be appropriate and effective in the treatment of said disease. (4) In that the statement on the label, "Magnesium carbonate, sodium phosphate, sodium chloride (salt), cascara, iron and ammonium citrate, saccharin, dextrose (grape sugar), caramel color (burnt sugar), magnesium sulfate (Epsom salt)," was misleading since it failed to reveal the material fact that the effect of the article was due essentially to its content of Epsom salt, that the other ingredients mentioned were present in relatively inconsequential amounts, and that some of them, namely, sodium chloride (salt), iron and ammonium citrate, saccharin, dextrose (grape sugar), caramel color (burnt sugar), were not active ingredients.

On September 15, 1941, and January 7, 1942, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

616. Misbranding of Hoyt's Compound. U. S. v. 29½ Dozen Packages and 32½ Packages of Hoyt's Compound. Default decree of condemnation and destruction. (F. D. C. No. 5182. Sample No. 52314-E.)

The labeling of this product failed to bear adequate directions for use and listed the ingredients in such a way as to create the impression that all were active; whereas all were not active. The labeling also bore false and misleading curative and therapeutic claims.

On August 2, 1941, the United States attorney for the Eastern District of Washington filed a libel against 29½ dozen 10-fluid ounce size packages and 32½ dozen 2-fluid ounce packages at Yakima, Wash., alleging that the article had been shipped in interstate commerce on or about May 27, 1941, by the Hoyt Chemical Co. from Denver, Colo.; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted essentially of water, alcohol, sugar, and extracts of plant materials including a laxative plant drug.

The article was alleged to be misbranded in that its labeling failed to bear adequate directions for use since the directions provided for continuous administration; whereas it was a laxative and should not be administered continuously. It was alleged to be misbranded further in that names of ingredients other than active ingredients appeared on the label thereby creating the misleading impression that all the ingredients listed were active ingredients. It was alleged to be misbranded further in that statements in the labeling which represented that it was an appropriate treatment for diseases of the stomach, bowels and kidneys; would be efficacious in the treatment of run-down conditions and for skin and blood diseases; that it would relieve such symptoms as sour stomach, bloating, indigestion, belching, gas, nervousness, dizziness, spots before the eyes, tiredness, sluggishness, and muscular aches and pains, were false and misleading since it contained no ingredients capable of producing the effects claimed.

On September 24, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.